

IN THE CLAIMS

This listing of claims will replace all prior versions, and listing, of claims in the application:

Listing of Claims:

1-6. (Canceled)

7. (Previously Presented) An integrated device comprising:

(a) a case;

(b) a pad;

(i) disposed within the case and,

(ii) capable of receiving and transporting a biological sample containing an

analyte;

(c) a detector:

(i) in fluid communication with the pad (b);

(ii) disposed within the case (a); and

(iii) adapted for at least one of detecting the presence and quantitating the

concentration of analyte in the sample;

(iv) said detector being capable of being in contact with a display for

illustrating results of the detector; and

(d) a strap or adhesive tape for holding the pad to an area of skin surface,

wherein:

(e) the case (a) includes at least one opening suitable to allow the biological sample containing analyte to contact the pad (b).

8. (Previously Presented) The integrated device of claim 7 wherein the pad (b) contains a surfactant to facilitate transport of the biological sample containing analyte across the pad (b).

9-31. (Cancelled)

32. (Previously Presented) The integrated fluid harvesting and analysis device of claim 64, and further comprising a sealed electrical connection to at least one of the sensor (c) and a probe via the first means.

33-50. (Cancelled)

51. (Previously Presented) A method for harvesting interstitial fluid from tissue and analyzing the interstitial fluid, said method comprising the steps of:

(a) porating a selected area of skin to form an opening for extracting a sample comprising interstitial fluid, which sample is suitable for quantitating an analyte;

(b) collecting the sample from the opening,

wherein:

(c) step (b) is enhanced by applying a vacuum to the selected area of the skin;

(d) the sample is collected in an article comprising:

(i) a pad capable of receiving the sample and

(ii) a strap or adhesive tape for holding the pad to the selected area of skin,

(e) the article contains an opening suitable to allow the sample to contact the pad; and

(f) determining the amount of analyte within the sample.

52-54. (Cancelled)

55. (Currently Amended) An apparatus for obtaining biological fluid for diagnostic testing, said apparatus comprising:

(a) a device ~~for forming an opening~~ configured to form an open hole in an area of skin suitable for extracting a sample comprising interstitial fluid;

(b) a vacuum ~~device for introducing~~ pump configured to introduce a vacuum onto the area of skin adjacent the hole so as to stretch the skin to enhance interstitial fluid flow from the skin;

(c) wherein the vacuum ~~device pump~~ is ~~capable of controlling~~ configured to control the ~~pressure level and/or timing~~ duration of the vacuum.

56. (Currently Amended) The apparatus according to claim 55 wherein the vacuum ~~device pump~~ is ~~capable of maintaining~~ configured to maintain the vacuum at a desired ~~pressure level~~.

57. (Currently Amended) An apparatus for obtaining biological fluid for diagnostic testing, said apparatus comprising:

(a) a first device for forming an ~~opening~~ open hole in an area of skin suitable for extracting a sample of biological fluid;

(b) a second device for introducing a positive pressure to the area of skin to assist in the fluid flow from the opening,

wherein:

(c) the second device is capable of controlling the timing and/or the amount of pressure on the area of skin.

58. (Currently Amended) The apparatus according to claim 57:

further comprising (d) a vacuum device for introducing a vacuum onto the ~~area of skin~~ open hole so as to enhance fluid flow from the opening;

wherein:

(e) the second device is capable of controlling the pressure level and/or timing of the vacuum.

59. (Previously Presented) The apparatus of claim 57 wherein the sample comprises blood.

60. (Previously Presented) The apparatus of claim 57 wherein the sample comprises interstitial fluid.

61 and 62. (Canceled)

63. (Previously Presented) An integrated fluid harvesting and analysis device, comprising:

(a) a first layer;

(b) a porating element:

(i) disposed on the first layer (a);

(ii) adapted for forming at least one opening in tissue;

(c) a sensor:

(i) positioned in fluid communication with the at least one opening in the tissue;

(ii) responsive to a biological fluid collected from the tissue to provide an indication of a characteristic of the biological fluid; and

(d) a mechanical element:

(i) having a small opening therein;

(ii) capable of receiving the first layer (a) and the sensor (c) such that the porating element (b) is aligned with the small opening; and

(iii) responsive to downward force thereon to cause the surface of the tissue to bulge into the small opening.

64. (Currently Amended) An integrated fluid harvesting and analysis device, comprising:

(a) a first layer;

(b) a porating element:

(i) for forming at least one opening in tissue;

- (ii) disposed on the first layer (a);
- (c) a sensor:
  - (i) positioned in fluid communication with the at least one opening in the tissue;
  - (ii) responsive to a biological fluid collected from the tissue to provide an indication of a characteristic of the biological fluid;
- (d) first means for pneumatically sealing the first layer (a) and the sensor (c) to the surface of the tissue and forming a sealed chamber; and
- (e) second means coupled to the first means ~~[[d]]~~ (d) for supplying negative pressure to the sealed chamber.

65. (New) A method for obtaining biological fluid for diagnostic testing comprising:

- (a) forming an open hole in biological tissue suitable for extracting a sample of biological fluid suitable for measuring a characteristic of the biological fluid;
- (b) extracting the sample from the open hole, wherein at least one of positive and negative pressure is applied to the surface of the biological tissue adjacent to the open hole in order to enhance the extraction of the sample.

66. (New) The method of claim 65 wherein the biological fluid comprises blood.

67. (New) The method of claim 65 wherein the biological fluid comprises interstitial fluid.

68. (New) A multi-layer assay device comprising:

- (a) a receiving layer capable of receiving a sample of biological fluid including an analyte and facilitating the movement of the fluid;
- (b) an analyte sensor capable of detecting the presence of analyte or measuring the concentration of analyte in the fluid; and

(c) a substrate layer configured to interface with a processing circuit, wherein the receiving layer (a) is located underneath at least a portion of the substrate layer (c) and facilitates the movement of the biological fluid to the sensor (b); and further wherein said assay device has at least one opening therein through all said layers through which a hole can be made in biological tissue.

69. (New) A multi-layer assay device comprising:

(a) a receiving layer capable of receiving a sample of biological fluid including an analyte and facilitating the movement of the fluid;

(b) an analyte sensor capable of detecting the presence of analyte or measuring the concentration of analyte in the fluid;

(c) a substrate layer that is configured to electrically connect to a processing circuit, and

(d) a bottom layer; wherein the receiving layer (a) is located underneath at least a portion of the substrate layer (c) and wherein said assay device has at least one opening therein through all said layers in through which a hole can be made in biological tissue.

70. (New) An integrated fluid harvesting and analysis device, comprising:

(a) a first layer for positioning in contact with tissue and through which poration of tissue is achieved such that at least one opening is formed in the first layer and at least one open hole is formed in the tissue;

(b) a sensor positioned in fluid communication with the at least one opening of the first layer, the sensor being responsive to a biological fluid collected from the tissue to provide an indication of a characteristic of the biological fluid.

71. (New) A method for harvesting biological fluid from tissue and analyzing the biological fluid, comprising:

a. providing a multi-layer integrated device comprising:

- (i) a receiving layer capable of receiving a sample of biological fluid including an analyte and facilitating the movement of the fluid;
  - (ii) an analyte sensor capable of detecting the presence of analyte or measuring the concentration of analyte in the fluid;
  - (iii) a substrate layer configured to interface with a processing circuit, and
  - (iv) a bottom layer; wherein the receiving layer (i) is located underneath at least a portion of the substrate layer (iii) and wherein said layer (iii) has at least one opening therein;
- b. forming an open hole in biological tissue suitable for extracting a sample of biological fluid suitable for measuring a characteristic of the fluid;
  - c. extracting the sample from the unobstructed skin opening and introducing the sample into the integrated device, wherein at least one of the positive and negative pressure is applied to the biological tissue adjacent to the hole in order to enhance the extraction of the sample; and
  - d. measuring a characteristic of the biological fluid.
72. (New) The method of claim 71 wherein the biological fluid comprises blood.
73. (New) The method of claim 71 wherein the biological fluid comprises interstitial fluid.
74. (New) A method for harvesting biological fluid from tissue and analyzing the biological fluid, comprising steps of:
- a. placing a layer in contact with a surface of tissue;

- b. forming at least one open hole in the tissue;
- c. collecting biological fluid from the tissue through at least one opening in the layer; and
- d. wetting a sensor that is positioned in fluid communication with the at least one opening in the layer with biological fluid to measure a characteristic of the biological fluid, wherein the process further comprises applying positive pressure to the layer so as to induce flow of biological fluid through the opening.

75. (New) A method of harvesting biological fluid from tissue and analyzing the biological fluid, comprising steps of:

- a. placing a layer in contact with a surface of tissue;
- b. forming at least one open hole in the tissue;
- c. collecting biological fluid from the tissue through at least one opening in the layer; and
- d. wetting a sensor that is positioned in fluid communication with the at least one opening in the layer with biological fluid to measure a characteristic of the biological fluid and wherein the process further comprises the step of creating a negative pressure to the skin so as to induce flow of biological fluid through the opening.

76. (New) An apparatus configured to obtain a sample of biological fluid through an area of skin for analysis in a diagnostic test, said apparatus comprising:

- (a) a device configured to form an open hole in said area of said skin through which the sample is to be extracted;
- (b) a pump configured to generate a vacuum for extracting said sample from said hole in said area of said skin, and



(c) means for controlling said pump, wherein said means for controlling said pump operates said pump to maintain said vacuum at a specified level.

77. (New) An apparatus configured to obtain a sample of fluid for analysis in a diagnostic test, said apparatus comprising:

- (a) a device for forming an open hole in an area of skin from which said sample is to be extracted; and
- (b) a vacuum pump for extracting said sample from said hole in said area of said skin;
- (c) wherein said apparatus has an end that contacts said area of said skin, said end being equipped with a seal, said seal surrounding an opening in said apparatus, said opening allowing communication between said area of said skin and a chamber in said apparatus, said seal preventing air from leaking into said chamber, so that said vacuum pump can provide sufficient suction action for stretching said skin, and for extracting said sample of fluid from said hole in said area of said skin.

78. (New) A method for performing a diagnostic test utilizing a sample of biological fluid, said method comprising the steps of:

- (a) forming an open hole in an area of skin from which said sample is to be extracted; extracting said sample from said hole in said area of said skin, with the aid of vacuum and stretching of the skin;
- (b) providing a multiple-layer article comprising:
  - i. a layer capable of receiving biological fluid and transporting the biological fluid received by means of a surfactant coated mesh;
  - ii. a layer capable of detecting the presence of analyte or measuring the amount of analyte in biological fluid; and

iii. a layer that can be placed in contact with a meter, the meter-contactable layer overlying the biological fluid-transporting layer, said layer (i) capable of transporting biological fluid to said layer (ii);

(d) allowing said extracted sample to be received by said biological fluid-transporting layer and allowing said biological fluid to be transported by said means of a surfactant coated mesh to said layer capable of detecting the presence of analyte or measuring the amount of analyte in biological fluid; and

(e) determining the presence of analyte or measuring the amount of analyte in biological fluid.

79. (New) A method for performing a diagnostic test utilizing a sample of biological fluid, said method comprising the steps of:

(a) forming a hole in an area of skin from which said sample is to be extracted;  
(b) extracting said sample from said hole in said area of said skin, with the aid of vacuum and stretching of the skin;

(c) providing a multiple-layer article comprising:

- i. a covering layer having an opening therein;
- ii. a layer, overlying the covering layer, capable of receiving biological fluid through the opening in the covering layer and transporting biological fluid by means of a surfactant coated mesh;
- iii. a layer that can be placed in contact with a meter, the meter-contactable layer overlying the biological fluid-transporting layer; and
- iv. a layer capable of detecting the presence of analyte or measuring the amount of analyte in biological fluid, which layer is disposed between the covering layer and the meter-contactable layer and is capable of receiving biological fluid from the fluid-transporting layer;

(d) allowing said extracted sample to be received by said fluid-transporting layer and allowing said biological fluid to be transported by said means of a surfactant coated mesh to said layer capable of detecting the presence of analyte or measuring the amount of analyte in biological fluid; and

(e) determining the presence of analyte or measuring the amount of analyte in biological fluid.

80. (New) A method for obtaining a sample of biological fluid for a diagnostic test, said method comprising the steps of:

(a) forming an open hole in an area of skin from which said sample is to be extracted;  
(b) extracting said sample from said hole in said area of said skin, with the aid of (1) a vacuum generated by a pump operated to maintain a desired level of vacuum and (2) stretching a portion of the skin in the vicinity of said hole, whereby sufficient biological fluid is collected for said diagnostic test.

81. (New) A multiple-layer element comprising:

(a) a layer capable of receiving blood and transporting the blood received by means of a surfactant coated mesh;  
(b) a layer capable of detecting the presence of analyte or measuring the amount of analyte in blood; and  
(c) a layer that can be placed in contact with a meter, the meter-contactable layer overlying the blood-transporting layer, said layer (a) capable of transporting blood to said layer (b), wherein said meter-contactable layer has at least one opening therein.

82. (New) The article of claim 81, wherein said blood-transporting layer comprises a wick.

83. (New) Multiple-layer article comprising:

(a) a covering layer having an opening therein;

(b) a layer, overlying the covering layer, capable of receiving blood through the opening in the covering layer and transporting blood by means of a surfactant coated mesh;

(c) a layer that can be placed in contact with a meter, the meter-contactable layer overlying the blood transporting layer; and

(d) a layer capable of detecting the presence or analyte or measuring the amount of analyte in blood, which layer is disposed between the covering layer and the meter-contactable layer and is capable of receiving blood from the blood-transporting layer, wherein said meter-contactable layer has at least one opening therein.